

CLAIMS:

1. (original) A method of removing sodium from an animal subject comprising administering to an animal subject in need thereof an effective amount of a sodium-binding composition comprising a sodium-binding polymer, said polymer having an *in vivo* sodium binding capacity of 4 mmol or more per gram of said polymer in a human.
2. (canceled)
3. (currently amended) The method of claim 1 ~~2~~ wherein said sodium-binding composition exhibits decreased permeability to said bound sodium in said lower gastrointestinal tract relative to the permeability exhibited by the sodium-binding composition to said bound sodium in the upper gastrointestinal tract.
4. (canceled)
5. (original) The method of claim 1 wherein said sodium-binding composition swells in an isotonic fluid environment.
6. (currently amended) The method of claim 1 ~~2~~ wherein said sodium binding ~~and/or sodium retention~~ by said sodium-binding composition is dependent on a pH of an environment surrounding said polymeric composition.
7. (currently amended) The method of claim 3 ~~2~~ wherein said sodium binding ~~and/or sodium retention~~ by said sodium-binding composition is dependent on a concentration of bile acids and/or fatty acids in an environment surrounding said polymeric composition.
8. (currently amended) The method of claim 3 ~~2~~ wherein said sodium binding ~~and/or sodium retention~~ by said sodium-binding composition is dependent on an activity of enteric enzymes in an environment surrounding said polymeric composition.
9. (original) The method of claim 1 wherein said sodium-binding composition comprises sulfonate or phosphonic polymers.
10. (currently amended) The method of claim 1 wherein said sodium-binding composition does not release ~~detrimental ions~~ Cl<sup>-</sup> or OH<sup>-</sup>.
11. (currently amended) The method of claim 1 ~~10~~ wherein said sodium-binding composition does not release detrimental ion is at least one of K<sup>+</sup>, Cl<sup>-</sup>, OH<sup>-</sup>, or Ca<sup>2+</sup>.
12. (currently amended) The ~~A~~ method of claim 1 ~~removing sodium from an animal subject comprising administering to an animal subject in need thereof an effective amount of a~~ wherein

~~the sodium-binding composition comprises comprising an acid resin, said resin having an *in vivo* sodium binding capacity of 4 mmol or more per gram of said resin in a human and said composition retains a bound sodium in a lower gastrointestinal tract.~~

13. (original) The method of claim 12 wherein said acid resin comprises repeat units charged with  $H^+$  or  $NH_4^+$  ions.

14. (currently amended) The method of claim 1 or 12 wherein said effective amount of sodium-binding composition administered is not greater than about 15 grams ~~gms~~ per day.

15. (original) The method of claims 1 or 12 wherein said sodium-binding composition removes about 50 mmol of sodium per day.

16. (original) The method of claim 1 or 12 wherein said sodium-binding composition comprises at least one of polyvinylsulfonate polymer, polyvinylsulfamate polymer, polyvinylsulfamate/vinylsulfate copolymer, polyvinylphosphoramidic polymer, N-(bis-phosphonic-ethyl) polyvinylamine polymer, poly- $\alpha$ -fluoroacrylic acid polymer, vinylphosphonate/acrylic acid copolymer, vinylphosphonate/ $\alpha$ -fluoroacrylic acid copolymer, polyvinylsulfate polymer, crosslinked polyvinylsulfamate polymer, or poly  $\alpha$ -acrylic acid polymer.

17. (currently amended) A method of removing sodium from an animal subject comprising administering to an animal subject in need thereof an effective amount of a core-shell composition comprising a cation exchange core and a semi-permeable shell, said cation exchange core being capable of binding sodium in an upper gastro-intestinal tract and the semi-permeable shell being characterized by decreased permeability to the bound sodium in a lower gastro-intestinal tract relative to the permeability exhibited by the sodium-binding composition to said bound sodium in the upper gastrointestinal tract.

18. (original) The method of claim 17 wherein the core has an *in vivo* sodium binding capacity of 4 mmol or more per gram of said resin in a human.

19. (original) The method of claim 17 wherein said core binds more sodium in said upper gastrointestinal tract in the presence of said shell component compared to amount of sodium bound by said core in the absence of said shell component.

20. (original) The method of claim 17 wherein said semi-permeable shell preferentially binds chloride.

21. (canceled)
22. (original) The method of claim 17 wherein said competing solute is at least one of  $K^+$ ,  $Mg^{++}$ ,  $Ca^{++}$ ,  $NH_4^+$ ,  $H^+$ , or protonated amines.
23. (original) The method of claim 21 wherein said semi-permeable shell is permeable to sodium ions at a pH of about 1 to about 5.
24. (original) The method of claim 17 wherein said core preferentially binds sodium in said upper gastro-intestinal tract and said semi-permeable shell is permeable to sodium ions at a pH of about 7 and above and said permeability to ions is decreased at a pH of about 5 to about 6.
25. (original) The method of claim 17 wherein said permeability of said semi-permeable shell is modulated by a binding of bile acids and/or fatty acids to said shell.
26. (original) The method of claim 17 where in said permeability of said semi-permeable shell is modulated by enteric enzymes or enzymes produced by colonic microflora.
27. (original) The method of claim 17 wherein said core comprises at least one of a polyvinylsulfonate polymer, a polyvinylsulfamate polymer, a polyvinylsulfamate/vinylsulfate copolymer, a polyvinylphosphoramidic polymer, a N-(bis-phosphonic-ethyl) polyvinylamine polymer, a poly- $\alpha$ -fluoroacrylic acid polymer, a vinylphosphonate/acrylic acid copolymer, a vinylphosphonate/ $\alpha$ -fluoroacrylic acid copolymer, a polyvinylsulfate polymer, a crosslinked polyvinylsulfamate polymer, or a poly  $\alpha$ -acrylic acid polymer and said shell comprises of at least one of a poly-11 trimethylammoniumundecylmethacrylate polymer, a styrene-vinylpyridine polymer, 11-dimethyl-aminodecylmethacrylate/laurylmethacrylate copolymer, or a polyallylamine/polystyrene sulfonate polymer.
- 28 - 34. (canceled)
35. (currently amended) The method of claim 1, 12, or 17, ~~or 28~~ wherein said animal subject is suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or sodium overload.
36. (original) The method of claim 35 wherein extra cellular water is removed from said animal subject.
37. (original) The method of claim 35 wherein a beneficial effect is observed on fluid management, blood pressure control, and/or interdialytic weight gain.

38. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein said animal subject is suffering from a disease characterized by a presence of abnormal quantities of sodium and/or water in the body of said animal subject.
39. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein said animal subject is resistant to diuretic treatment and is suffering from hypertension, chronic heart failure, end stage renal disease, liver cirrhosis, chronic renal insufficiency, fluid overload, or a combination thereof.
40. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein a small amount of sodium is removed from the animal subject over an extended period of time.
41. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein treatment of said animal subject prevents formation of edema after a cardiac event.
42. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein said animal subject is suffering from volume/salt sensitive diastolic heart failure.
43. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein said composition is co-administered with a diuretic, an ACE inhibitor, an  $\alpha$ - blocker, a  $\beta$ - blocker, an angiotensin II receptor blocker, or a combination thereof.
44. (currently amended) The method of claim 1, 12, or 17,~~or 28~~ wherein said composition is co-administered with a laxative.
45. (new) The method of claim 1 wherein said sodium-binding polymer has an *in vitro* sodium binding capacity of equal to or more than 6 mmol per gram of polymer at a pH of about 7.5.
46. (new) The method of claim 1 wherein the *in vivo* sodium binding capacity is 5 mmol or more per gram of said polymer.
47. (new) The method of claim 1 wherein the *in vivo* sodium binding capacity is 6 mmol or more per gram of said polymer.
48. (new) The method of claim 1 wherein the *in vivo* sodium binding capacity is 8 mmol or more per gram of said polymer.
49. (new) The method of claim 1 wherein the sodium binding capacity is calculated by measuring the amount of sodium in the feces after administration of the sodium-binding polymer to a human patient.

50. (new) The method of claim 47 wherein the sodium binding capacity is calculated by measuring the amount of sodium in the feces after administration of the sodium-binding polymer to a human patient.
51. (new) The method of claim 1 wherein said sodium binding polymer comprises a crosslinked polymer.
52. (new) The method of claim 17 wherein the semi-permeable shell comprises a crosslinked polymer.
53. (new) The method of claim 17 wherein the semi-permeable shell comprises a polymer containing hydrophobic monomers and monomers that ionize subject to pH change.
54. (new) The method of claim 53 wherein the hydrophobic monomers are long chain alcohol (meth)acrylates, N-alkyl (meth)acrylamide, aromatic monomers.
55. (new) The method of claim 53 wherein the monomers that ionize subject to pH change are basic monomers that ionize at low pH and remain neutral beyond their  $pK_a$ .
56. (new) The method of claim 55 wherein the basic monomers are vinyl pyridine or dialkylaminoethyl (meth)acrylamide.
57. (new) The method of claim 55 wherein said semi-permeable shell has low permeability to sodium ions at neutral pH.
58. (new) The method of claim 53 wherein the monomers that ionize subject to pH change are acidic monomers that ionize at neutral pHs and above.
59. (new) The method of claim 58 wherein said semi-permeable shell has low permeability to sodium ions at pH 5 to 6.